### **ADDITIONAL FEES**

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#### **REMARKS**

Claims 8-15 are in the application. Claims 9 and 13 have been canceled and claims 8 and 12 have been amended as shown above.

New claims 16-23 have been added. These claims are supported by the specification, e.g., pages 12-20, and do not introduce any new matter.

Claim 8 was rejected under 35 U.S.C. § 102(b) over publication number WO/95/19108 to Sanchez et al., ("Sanchez").

Claims 9-15 were rejected under 35 U.S.C. § 103(a) over Sanchez.

Applicants have amended claims 8 and 12 to specify a cyclodextrin composition distinct from Sanchez. The amended claims 8 and 12, now recite that the percentage of γ-cyclodextrin, by weight, of the total cyclodextrins must be at least 30%. This amendment, in effect, incorporates the limitations from now-canceled claims 9 and 13, respectively. Support for this amendment is found on page 8, lines 6-9 of the specification.

# Sanchez Does not Anticipate or Render Obvious the Amended Claims

To anticipate, a reference must teach each claim limitation. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

As discussed below in detail, Sanchez does not disclose, claim or exemplify a mixture of cyclodextrins requiring that at least 30% of the cyclodextrin, by weight, be y-cyclodextrin. Accordingly, Sanchez cannot anticipate the amended claims.

Applicants respectfully request that the rejection under § 102(b) be withdrawn.

Applicants have amended claims 8 and 12 to recite an important and distinguishing feature. Specifically, the added weight-percent limitation refers to the percentage of  $\gamma$ -cyclodextrin in relation to the <u>total amount of cyclodextrins</u> present, and <u>not to the final weight of the formulation</u>.

By doing so, the claim unambiguously expresses a minimum requirement for  $\gamma$ -cyclodextrin relative to other cyclodextrins. Sanchez does not disclose any such requirement. In fact, most of his exemplified embodiments disclose use of only  $\beta$ -cyclodextrin.

Nor does he disclose <u>any</u> cyclodextrin mixtures comprising <u>any</u> preferred composition of cyclodextrins. At most he merely specifies that  $\beta$ - and  $\gamma$ - cyclodextrins are particularly useful, without providing <u>any quantitative guidance</u> as to how to formulate his compositions. See Sanchez, page 2, lines 30-31.

Examiner incorrectly cites Sanchez, claims 6-11 as teaching a mixture of cyclodextrins,  $\alpha$ ,  $\beta$ , and  $\gamma$ , from 1-30%. Claim 6 merely recites a "composition comprising cyclodextrins." Which cyclodextrins? How much of each? It is respectfully suggested that this cannot reasonably be viewed as rendering Applicants' claim 8 and 12 as being obvious.

Sanchez's claim 9 recites "<u>the</u> cyclodextrin" and claim 11 recites the Markush group from which a cyclodextrin can be chosen.

Further, Sanchez's claim 12 relates specifically to cavity <u>sizes</u>, <u>not types</u>. Thus, he refers to a mixture of different <u>sized</u> cyclodextrins or perhaps those having different hydrophobic side groups.

In sum, Sanchez does not disclose <u>any mixtures</u> of cyclodextrins. Not one of his examples demonstrates use of a mixture or discloses a preferred composition.

It is respectfully suggested that the Examiner has read into Sanchez's disclosure and claims, a mixture of  $\alpha$ ,  $\beta$  and  $\gamma$  cyclodextrins. Examiner then relies on the level of the skill in the art to render the claims herein, unpatentable. Office Action, page ¶¶ 3-4.

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Without a solid line of technical reasoning or other evidence, reliance on the level of skill is an improper basis to reject claims. MPEP § 2143.01. The fact that Sanchez's disclosure can be modified to approximate Applicants' claims is not sufficient. There must be sufficient objective teaching to provide the necessary guidance and motivation. MPEP § 2143.01.

Accordingly, the rejection under § 103(a) should be withdrawn.

# Sanchez's Disclosure and Claimed Composition Teach Away From Applicants' Invention

Newly added dependent claims 16-23, recite limitations to components that would not be found in "basically dry solids or aqueous solutions comprising empty (uncomplexed) cyclodextrins." Sanchez, page 2, lines 26-28.

Sanchez specifically claims and teaches the desirability of employing "empty" cyclodextrins in his topical compositions. See Sanchez, page 2, lines 8-36. These cyclodextrins are those that do not have their inner hydrophobic cavity complexed with hydrophobic molecules. Page 8, lines 19-20. This requirement is also recited in Sanchez's claim 1.

It is clear that Sanchez's cyclodextrins are not the same as those in dependent claims 16-23. One with ordinary skill in the pharmaceutical and cosmetic arts would have no trouble discerning the different nature of Sanchez's and Applicants' compositions.

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Accordingly, it is respectfully requested that in view of the amendments and the foregoing comments, that all of the rejections under §§ 102(b) and 103(a) over Sanchez be withdrawn.

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# **CONCLUSION**

The Applicants have demonstrated important distinctions between Applicants' inventions and Sanchez's that render the rejections under §§ 102(b) and 103(a) improper.

Sanchez does not disclose even one mixture of cyclodextrins, let alone a mixture specifying a quantitative preference for any specific cyclodextrin. The Examiner has not indicated how one with ordinary skill in the art would use Sanchez to arrive at the Applicants' claims. Accordingly, a *prima facie* case of unpatentability has not been established.

In view of the foregoing amendments and remarks, allowance of all claims is respectfully solicited.

Respectfully submitted

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### **MARKED UP VERSION OF CLAIMS**

8. (Amended) A method for reducing the production of sebum or for removing sebum, said method comprising topically applying to skin and/or hair an effective amount therefor of a composition comprising a cyclodextrin component, said component having one or more cyclodextrins, wherein said one or more cyclodextrins are selected from the group consisting of α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, δ-cyclodextrin, and at least 30% by weight of said cyclodextrin component comprises γ-cyclodextrin.

12. (Amended) A method for controlling at least one condition selected from the group consisting of blemished skin, acne, seborrheic phenomena, greasy hair, said method comprising topically applying to an area of skin and/or hair affected by increased sebum production an effective amount therefor of one or more cyclodextrins a composition comprising a cyclodextrin component, said component having one or more cyclodextrins, wherein said one or more cyclodextrins are selected from the group consisting of α-cyclodextrin, β-cyclodextrin, γ-cyclodextrin, δ-cyclodextrin, and at least 30% by weight of said cyclodextrin component comprises γ-cyclodextrin.

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